

REMARKS

Upon entry of the above amendment, claims 1-6 and 8 will be pending in the present application. Claim 1 has been amended. No new matter has been added. Claims 7 and 9 have been cancelled without prejudice or disclaimer.

Claim 1 has been amended, and claims 7 and 9 have been canceled, for the sole reason of advancing prosecution. Applicants, by amending or cancelling any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

Independent claim 1 has been amended to recite "a patch-containing packaging pouch comprising: a packaging pouch comprising a polyacrylonitrile layer on the innermost side; and a patch housed within the packaging pouch comprising a support and a pressure-sensitive adhesive layer is formed on one side of a support, and the pressure-sensitive adhesive layer is formed of a pressure-sensitive adhesive composition comprising a pressure-sensitive adhesive comprising at least one compound selected from the group consisting of a styrene-isoprene-styrene block copolymer, polyisobutylene and an acrylic polymer, and bisoprolol or a pharmaceutically acceptable salt thereof, present in an amount of 1 to 50% by mass in the pressure-sensitive adhesive composition, wherein relative humidity inside the packaging pouch at 25°C is maintained at 25% or less." Support for amended claim 1 can be found throughout the specification and claims as originally filed. For example, please see

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paragraphs [0038]-[0039] on page 12 of the present specification. No new matter has been added.

Claims 2-6 and 8 all depend, either directly or indirectly, from claim 1.

Applicants respectfully submit that the amendment of claim 1 does not add any new matter within the meaning of 35 USC §132. Accordingly, entry of the amendment is respectfully requested.

In view of the remarks set forth herein, further and favorable consideration is respectfully requested.

1. ***At pages 2-5 of the Official Action, claims 1-6 and 8 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Wilking (U.S. Patent No. 5,698,217) in view of Klokke et al. (U.S. Patent Application Publication No. 2004/0086552), in view of Kanios et al. (U.S. Patent No. 6,905,016) in view of Higo et al. (U.S. Patent No. 5,866,157) in further view of Asmussen et al. (U.S. Patent No. 6,267,982).***

The Examiner asserts that it would have been obvious to combine the transdermal drug delivery system of Wilking with the transdermal therapeutic system containing bisoprolol as described in Klokke et al. and the acrylic polymer pressure-sensitive adhesive as described in Kanios et al. with the drug content of 1 to 50% by mass as described by Higo et al. and the relative humidity inside the packaging pouch of between 5% and below 0.5% as described by Asmussen et al. to arrive at the presently claimed subject matter.

In view of the following, Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International*

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Co. v. Teleflex Inc. et al., 550 U. S. 398 (2007), “a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” (*KSR*, 550 U.S. at 417). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

It is submitted that a proper case of *prima facie* obviousness has not been established because, whether taken alone or together, none of the cited references teach or suggest all the limitations of the claims as required by *In re Wilson*.

As amended, claim 1 is directed to a patch-containing packaging pouch comprising: a packaging pouch comprising a polyacrylonitrile layer on the innermost

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side; and a patch housed within the packaging pouch comprising a support and a pressure-sensitive adhesive layer is formed on one side of a support, and the pressure-sensitive adhesive layer is formed of a pressure-sensitive adhesive composition comprising a pressure-sensitive adhesive comprising at least one compound selected from the group consisting of a styrene-isoprene-styrene block copolymer, polyisobutylene and an acrylic polymer, and bisoprolol or a pharmaceutically acceptable salt thereof, present in an amount of 1 to 50% by mass in the pressure-sensitive adhesive composition, wherein relative humidity inside the packaging pouch at 25°C is maintained at 25% or less. Claims 2-6 and 8 all depend, either directly or indirectly, from claim 1.

In contrast to the presently claimed subject matter, Wilking describes a transdermal drug delivery device including a carrier containing a dissolved drug. According to Wilking, the device also includes a desiccant package that is inert to the carrier, permeable to water vapor, and defines a desiccant compartment containing a desiccant. Further, according to Wilking, the device also includes a water vapor impermeable product package that contains the carrier and the desiccant package. See Wilking at the Abstract.

However, Wilking does not teach or suggest every element of the present subject matter. Nowhere does Wilking describe that the packaging pouch comprises a polyacrylonitrile layer on the innermost side, as recited in currently amended claim 1.

Klokkers et al. do not remedy the deficiencies of Wilking. Klokkers et al. describe a transdermal therapeutic system comprising a surface layer which is impervious with

respect to an active ingredient; a self-adherent matrix layer or a plurality of matrix layers, wherein the exposed matrix layer is self-adherent when the system is applied. According to Klokke et al., the transdermal therapeutic system also comprises a pull-off protective coating, whereby the matrix layer(s) contain one or more active ingredients and/or one or more biologically active substances and highly dispersed silicon dioxide. See Klokke et al. at the Abstract.

However, like Wilking, Klokke et al. do not teach or suggest every element of the present subject matter. Klokke et al. do not describe that the packaging pouch comprises a polyacrylonitrile layer on the innermost side, as presently claimed.

Kanios et al. do not remedy the deficiencies of Wilking and Klokke et al. Kanios et al. describe a device and method for stabilizing a drug in a carrier composition of a transdermal delivery system by providing a product packaging system to prevent or control degradation reactions. See Kanios et al. at the Abstract.

However, like Wilking and Klokke et al., Kanios et al. do not teach or suggest every element of the present subject matter. Kanios et al. do not describe that the packaging pouch comprises a polyacrylonitrile layer on the innermost side, as presently claimed.

Higo et al. do not remedy the deficiencies of Wilking, Klokke et al., and Kanios et al. Higo et al. describe a matrix type patch formulation comprising an adhesive layer containing a physiologically active substance, an organic acid, a hydrophobic material, a tackifying resin, a plasticizer and an absorption enhancer. See Higo et al. at the Abstract.

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However, like Wilking, Klokke et al., and Kanios et al., Higo et al. do not teach or suggest every element of the present subject matter. Higo et al. do not describe that the packaging pouch comprises a polyacrylonitrile layer on the innermost side, as presently claimed.

Asmussen et al. do not remedy the deficiencies of Wilking, Klokke et al., Kanios et al., and Higo et al. Asmussen et al. describe transdermal pharmaceutical preparation for the release of the active substance 17- β -estradiol. See Asmussen et al. at the Abstract.

However, like Wilking, Klokke et al., Kanios et al., and Higo et al., Asmussen et al. do not teach or suggest every element of the present subject matter. Asmussen et al. do not describe that the packaging pouch comprises a polyacrylonitrile layer on the innermost side, as presently claimed.

Applicants respectfully submit that a proper case of *prima facie* obviousness has not been established because, whether taken alone or together, none of the cited references teach or suggest all the limitations of the claims as required by *In re Wilson*. In particular, none of the cited references teach or suggest that the packaging pouch comprises a polyacrylonitrile layer, an aluminum foil layer, and a polyethylene terephthalate layer, in that order, starting from the innermost side of the packaging pouch, as presently claimed. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

2. ***At page 6 of the Official Action, claim 9 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Wilking, Klokke et al., Kanios et al., Higo et al., and Asmussen et al. and in further view of Takayuki (Japanese Patent Application No. 61-073547).***

The Examiner asserts that it would have been obvious to modify the innermost layer of the packaging pouch of Wilking and Klokke et al. to include a polyacrylonitrile-based resin as its innermost layer as described in Takayuki et al. As discussed above, Wilking describes a transdermal drug delivery device involving a carrier containing a dissolved drug. See Wilking at the Abstract. Klokke et al. describe a transdermal therapeutic system comprising a surface layer which is impervious with respect to an active ingredient; a self-adherent matrix layer or a plurality of matrix layers, wherein the exposed matrix layer is self-adherent when the system is applied. See Klokke et al. at the Abstract.

Takayuki describe "an anti-inflammatory, analgesic drug packaging body formed by affixing a peel-off protective film configured from a polyacrylonitrile-based resin on the drug-coated surface of a film-like or sheet-like anti-inflammatory, analgesic drug, and packaging and hermetically-sealing the same in a bag having an innermost layer of polyacrylonitrile-based resin which forms the innermost layer of the bag." See Takayuki et al. at page 2.

Applicants respectfully note that claim 9 has been canceled without prejudice or disclaimer, thereby rendering this rejection of claim 9 moot. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

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CONCLUSION

Based upon the above remarks and amendment, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw all rejections and allow all pending claims in this application. Favorable action with an early allowance of the claims pending in this application is earnestly solicited. The Examiner is welcomed to telephone the undersigned attorney if he has any questions or comments.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,
THE NATH LAW GROUP

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A handwritten signature in black ink, appearing to read 'Gary M. Nath', written over a horizontal line.

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